REMARKS

Reconsideration and withdrawal of the rejections of the application and consideration and entry of this paper and consideration and making of record the patents cited herein are respectfully requested in view of the amendments and remarks herewith and the matters discussed with the Examiner, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 2, 17-19, 21, 23-28, 31, 32, 43-60, 62 and 63 are under examination in this application. Claims 1, 2, 24, 25, 31, 32, 54, 55 and 63 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 4-6, 8, 12-16, 30, 34-36, 38, 42, 65-90 and 94-107 are cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter has been added by these amendments. Support for reduction of viral load of PCV-2 can be found in Example 10, particularly on page 38, *inter alia*.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support is found throughout the specification and from the pending and originally filed claims. Further, changes to the claims herein are not narrowing amendments. Accordingly, no estoppel as to equivalents arises from or is intended by this paper.

II. THE OBJECTIONS ARE OVERCOME

Claims 88-90 were objected to as being dependent upon a non-elected claim. These claims have been cancelled, obviating the objection.

III. THE DOUBLE PATENTING REJECTION IS OVERCOME

Claims 4-6, 8, 34-38, 42 and 65-81 of this application allegedly conflict with claims 4-6, 8, 34-38, 42 and 65-81 of U.S. application Serial No. 09/583,350. These claims are

drawn to non-elected subject matter and are cancelled by this amendment, rendering the double patenting rejection moot.

The Examiner is advised: that the instant application cites U.S. applications Serial Nos. 09/161,092, 09/082,558, 09/232,468 and 09/347,594; that those applications are now U.S. Patents Nos. 6,391,314, 6,368,601, 6,207,165 and 6,217,883; and that the Examiner should be aware of those patents, e.g., because she is the Examiner on at least three of those patents, for instance U.S. Patents Nos. 6,391,314, 6,368,601 and 6,217,883. The Examiner is respectfully requested to formally make of record U.S. Patents Nos. 6,391,314, 6,368,601, 6,207,165 and 6,217,883. A PTO-1449 listing these patents is enclosed in duplicate. The undersigned will gladly supply a copy of these patents (although it is believed that the Examiner has access to these patents).[1] For the Examiner's convenience, the front page and claims of each patent are enclosed.

In addition, as to the Examiner's statement that "[t]he '092 application, now US Patent 6,391,314 B1, does not encompass reducing disease caused by PCV-2."[2] For the record, it is noted: that claims of the 314 patent are directed to immunogenic compositions and methods for inducing an immunological response; that an immunogenic composition can elicit an immune or immunological response; and, that an immune or immunological response can be a protective immune or immunological response, e.g. an immunogenic composition can be a vaccine.

IV. THE REJECTIONS UNDER 35 U.S.C. § 112, 2ND PARAGRAPH, ARE OVERCOME

Claims 1, 2, 17-19, 21, 23-28, 31, 32, 43-60, 62, 63 and 82-90 were rejected 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claims 82-90 are cancelled, obviating the rejection of those claims.

The remaining claims were rejected because, according to the Office Action, "it cannot be determined whether the instant PCV-2 polypeptides are eliciting an immunogenic response as apposed [sic] to an antigenic response induced by the PCV-2 antigens". (Page 4). The claims have been amended to recite a composition for reducing viral load, rather than for eliciting an immune response. Therefore, the rejection on this basis is moot.

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[1] If the Examiner desires, the undersigned could even email her pdf versions of the patents.

[2] This is yet another reason why the patents mentioned in the main text that correspond to applications cited in the present application should be formally made of record; namely, the Examiner has been considering them (or at least one or some of them).

Claims 24-28 and 54-59 were rejected because the ORFs in the claims were allegedly ambiguous. The Examiner is thanked for her suggested amendment to obviate the rejection, which amendment was made without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Further this amendment was not a narrowing amendment, hence no estoppel as to equivalents is intended or should arise.

Reconsideration and withdrawal of the Section 112, second paragraph, rejections are requested.

V. THE REJECTIONS UNDER 35 U.S.C. § 112, 1ST PARAGRAPH, ARE OVERCOME

The Application Provides an Adequate Written Description

Claims 1, 2, 7, 17-19, 21, 23-28, 31, 32, 37, 43-60, 62, 63 and 82-90 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. Claims 82-90 are cancelled, obviating the rejection of those claims. The rejection of the remaining claims is traversed.

The Office Action contends that the disclosure lacks adequate written description for PCV-2 antigens because they are defined by function only and not structure. The Examiner's attention is respectfully drawn to U.S.S.N. 09/347,594, now U.S. Patent No. 6,217,883 and U.S.S.N. 09/161,092, now U.S. Patent No. 6,391,314, both of which were examined by the present Examiner and are incorporated by reference into the instant application. The recitation of "PCV-2 antigen" was accepted and allowed in both of those issued patents. Thus, it is submitted that Applicants clearly had possession of the claimed invention, and the written description rejection under 35 U.S.C § 112, first paragraph, is overcome.

The Application Provides an Enabling Disclosure

Claims 1, 2, 7, 17-19, 21, 23-28, 31, 32, 37, 43-60, 62, 63 and 82-90 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Claims 82-90 are cancelled, obviating the rejection of those claims. The rejection of the remaining claims is traversed.

It is argued in the Office Action that there is insufficient data to demonstrate that PCV-2 elicits the desired immune response to reduce PCV-2-caused pathologies. The claims have been amended to recite a reduction in viral load, rather than elicitation of an immune response. As admitted at page 7 of the current Office Action, the Declaration by Dr. Charreyre, filed with the

previous response, "clearly demonstrates antibody titer and low viral secretion". Therefore, the amendment to the claims should overcome the rejection on this basis.

It is respectfully submitted that adequate guidance is provided to enable the skilled artisan to practice the claimed invention without undue experimentation. Therefore, reconsideration and withdrawal of the U.S.C. § 112, first paragraph rejections are earnestly solicited.

CONCLUSION

No fee is believed to be due for consideration and entry of this paper, however, the Commissioner is hereby authorized to charge any fee occasioned by this paper to Deposit Account No. 50-0320.

In view of the remarks and amendments herewith and the matters discussed with the Examiner, the application is believed to be in condition for allowance. Consideration and entry of this paper, consideration and making of record the patents mentioned herein, favorable reconsideration of the application and reconsideration and withdrawal of the objections to and/or rejections of the application, and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date; and, if any issue remains as an impediment to allowance, a further interview is respectfully requested, with the Examiner invited to contact the undersigned to arrange a mutually convenient time and manner therefor.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. (Thrice amended) A composition for [eliciting an immune response and thereby] reducing viral load of porcine circovirus-2 (PCV-2)[-caused myocarditis, and/or abortion and/or intrauterine infection] in a pig[population of pigs] comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 polypeptide.

2. (Thrice amended) A composition for [eliciting an immune response and thereby] reducing viral load of PCV-2[-caused myocarditis and/or abortion and/or intrauterine infection associated with PCV-2] comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 antigen.

24. (Twice amended) The composition of claims 1 or 2, wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13 of a PCV-2 strain.

25. (Amended) The composition of claim 17 wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13 of a PCV-2 strain.

31. (Thrice amended) A method for reducing viral load[minimizing the symptoms] of porcine circovirus-2 (PCV-2)[-caused myocarditis, and/or abortion and/or intrauterine infection] in a pig[population of pigs] comprising inducing an immunological or immunogenic response against PCV-2 in the pig[population of pigs] comprising administering to the pig[population of pigs] the composition of claim 1.

32. (Thrice amended) A method for reducing viral load[minimizing the symptoms] of PCV-2[-caused myocarditis and/or abortion and/or intrauterine infection] in a pig[population of pigs] comprising inducing an immunological or immunogenic response against PCV-2 in the pig[population of pigs] comprising administering to the pig[population of pigs] the composition of claim 2.

54. (Twice amended) The method of claims 31 or 32, wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13 of a PCV-2 strain.

55. (Twice amended) The method of claim 47, wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13 of a PCV-2 strain.

63. (Amended) The method of claims 31 or 32, wherein the pig is a[population includes one or more] pregnant female pig[s and the administering is during pregnancy of the one or more female pigs].